REMARKS

As to the showing of a trigger, we have revised the specification so as to make this unnecessary.

In any event, as the Examiner knows, U.S. patents in this art do not necessarily show a trigger, because everyone skilled in the art is perfectly familiar with the trigger mechanism shown in any number of U.S. patents.

Moreover, in U.S. Patent 6,270,479, copy attached, in column 12, line 64 thereof (marked in yellow highlighter), it was approved that the trigger be mentioned but not shown. In any event, our amendment to the specification avoids the question altogether.

Reconsideration is respectfully requested, for the rejection of the claims as anticipated by GABRIEL.

The Final Rejection states, in the Response to Arguments, that

> "With regard to linear movement of the O-ring, GABRIEL et al. discloses the O-ring frictional slip clutch system (column 8, line 64 to column 9, line 5 and claim 10) and includes the use of variations on the concept.
>
> Besides the presents of rotational friction also implies the presents of linear friction".

However, we believe the operation of GABRIEL et al. has been misunderstood.

To recapitulate the background and objectives of the present invention, the problem that the inventors are looking at relates to injection devices where a single drive spring is used

both to move the syringe and needle from a safe retracted position to an injecting position in which the needle is projecting forwardly of the housing, and also, once the syringe is in that position, to expel the dose from the syringe. One of the problems in such devices is that, unless suitable measures are taken, the drive spring will start expressing the dose from the syringe before it penetrates the tissue of the user. This pre-dribble can be a problem particularly where the actual dosage is small.

There have been many mechanisms which seek to address this problem, for example with latches and escapement mechanism and the like which ensure that the thrust of the drive spring is initially applied solely to drive the syringe forward (and is positively isolated from the bung in the syringe), whereafter the spring thrust is then applied directly to the bung. Such mechanisms require numerous components which adds to their complexity and therefore manufacturing and assembly costs.

In the present invention this problem is solved by the use of an O-ring which is positioned between the plunger and the syringe container with the plunger initially being spaced rearwardly from the syringe bung so that when the drive force is transmitted to the plunger, the plunger, O-ring and syringe container move forwardly as one to extend the syringe to its projecting position without any force transmitted to the syringe bung. As soon as the needle penetrates the tissue of the user,

the reaction force created means that the friction force supplied between the O-ring and the plunger is overcome so that the plunger can move forwardly relative to the syringe container and the O-ring to engage the bung and expel the dose.

Looking now at GARBRIEL et al., the Examiner has cited the O-ring coupling 98 as being relevant to the present claim. In general terms however, the O-ring 98 in GABRIEL et al. is part of the dose setting mechanism and plays no active part in controlling the forward movement of the syringe container and the subsequent expulsion of the dose. Indeed, GABRIEL et al. is not at all concerned with the problem of pre-drop as discussed above; in fact, in column 10, lines 25-34, the reader is specifically instructed to screw out the plunger 18 to cause it to press against the piston element (i.e., bung) within the ampule (i.e., syringe container) to expel a drop from the tip of the needle.

Looking in more detail at GABRIEL et al., the function of the O-ring 98 is to act as a slip coupling or slip clutch to permit rotary movement to be transmitted between the flange 74 of a flanged sleeve 70 and the flanged 94 of a sleeve 92 (see Figures 2 and 4 and column 8, lines 63 to column 9, line 35). The flanged sleeve 70 is secured to the adjustment member 65 by a lock screw (column 7, lines 38 to 46 view 'O' ring 98) and so rotation of the adjustment member 65 is transmitted to the sleeve 92 unless the plunger lengthening mechanism 72 to which sleeve 92 itself transmits rotation is blocked against rotation (because

the plunger 18 has reached its full extension). In this instance, the 'O' ring 98 instead of transmitting rotation between sleeves 70 and 92 will slip (see column 9, lines 30 to 35). In other words, the element 98 simply provides a rotary clutch with a torque-limiting feature. There is no disclosure whatsoever of there being a frictional force applied between the O-ring 98 and the plunger lengthening mechanism tubular element 77 which extends therethrough. To suggest that O-ring 98 would exert a frictional engagement of item 77 is pure conjecture as GABRIEL et al. make no mention at all of any frictional engagement between O-ring 98 and item 77. Indeed, on an assessment of the GABRIEL et al. reference we cannot see any reason or motivation for making O-ring 98 a frictional fit on item 77. The O-ring 98 does not serve any active purpose in the linear interaction between the plunger and syringe bung or plug.

It is therefore incorrect to say that the presence of rotational friction implies the presence of linear friction; GABRIEL et al. is concerned to provide frictional engagement between two rotating sleeves whereas the present invention is concerned with providing frictional engagement between the plunger and the syringe container.

Looking specifically at the wording of main claim 7, GABRIEL et al. fails to disclose:

. The plunger carrying a surrounding and gripping flexible O-ring.

. The plunger carrying an O-ring which rests against an enlarged head of the other end of the syringed container.

. The lack of disclosure of "gripping" means that there is no disclosure of the feature of a primary movement of the plunger transmitting a frictional force to the O-ring.

. There is no disclosure of the syringe container being moved by and with the O-ring linearly.

. There is no disclosure of the feature of a resting of further movement of the syringe resulting in the frictional grip between the plunger and the O-ring being overcome.

. There is no disclosure of the primary and secondary movements of the plunger whereby in the primary mode the plunger, O-ring and syringe container all move as one whereas in the secondary mode the plunger moves relatively to the O-ring (and also the syringe container).

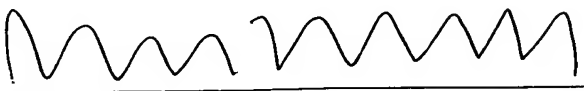
For these reasons the present invention as claimed is patentably distinguished from GABRIEL et al. The only common matter is that of an O-ring to provide a slip coupling. But the nature of the components and the function of the mechanisms are hugely different.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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APPENDIX:

The Appendix includes the following item(s):

- Col. 12, line 64 of U.S. Patent 6,270,479

release is controlled by an increased force generated at the piston contact with container front. Here a damper, especially a viscous damper, will give fall control over the force increase as during movement of the injection head the damper secures a predetermined reduction of the injection drive nominal force through energy consumption whereas at stop of the movement the damper is inactivated and said full nominal force is restored between drive and plunger head. Similarly at gradual retardation of the injection head the force increase will be correspondingly gradual. All in all a substantial force difference will be available for use by the control system in performing release of the autoreturn function. When, in a preferred manner this principle is applied in the conveyor type arrangement included in the autoinjection mechanism, as earlier described, the gradual force buildup and substantial force difference provided by the damper allow i. a. a long conveyor movement and significant force difference between injection drive force and conveyor counterforce, all serving to make the autoreturn release reliable, rugged and adaptive.

Further details of the invention will be cident form the description of specific embodiments in relation to the drawings.

SUMMARY OF DRAWINGS

FIGS. 1A to 1D show schematically in section four operational stages of a first embodiment of an autoinjector having a common drive for autopenetration and autoinjection and having elastic dampers.

FIGS. 2A to 2G show schematically in section seven operational stages of a second embodiment of an autoinjector having a common drive for autopenetration and autoinjection and being modified for a viscous damper.

FIGS. 3A to 3J show schematically in section ten operational stages of a third embodiment of an autoinjector having a separate drives for autopenetration and autoinjection and having a viscous damper being arranged for force determined autoreturn release.

FIG. 4 shows a modification of the autoinjector of FIG. 3 in which a linear damper is used.

DESCRIPTION OF DRAWINGS

FIGS. 1A to 1D show schematically in section four operational stages of a first embodiment of an autoinjector having a common drive for autopenetration and autoinjection and having elastic dampers. In FIG. 1A the autoinjector is in an initial cocked position before triggering. FIG. 1B shows the device after the autopenetration step, bringing the needle to an exposed position. FIG. 1C shows the device during the injection phase when the piston has been brought to an intermediate position within the container. FIG. 1D shows the device after that the autoreturn mechanism has moved the syringe back into a needle-hidden position. The autoinjector, generally designated **100**, comprises a housing **110**, divided into a rear housing part **111**, essentially confining the mechanism parts, and a front housing part **112**, essentially confining the container parts. The housing parts are separable, allowing insertion and replacement of containers, generally designated **120**, and comprising a barrel **121**, a front part **122** with attached needle **123**, a rear fingergrip part **124** and a piston **125** inserted in the barrel onto which piston a plunger **126** acts. A removable needle cover **127** initially protects the needle. The front housing part **112** also contains a container carrier, generally designated **130**, comprising an axially movable seat **131** for reception of containers, a flexible insert **132** allowing

accommodation of containers of different diameters, which insert has inwardly tapering surfaces **133** arranged to restrain container front **122** from forward movements relative the carrier and being pushed by inner sleeve structure **113** on the front housing part to an engaging position at least when the carrier is in the needle exposing position. A return spring **134** is arranged between the front housing part **112** front end and carrier **130** for movement of the carrier in the rearward direction. The seat has a knob **135** extending laterally through a slit in the hosing front part to an externally accessible position for manual movement of the carrier forwards against the bias of the return spring, e.g. for removal or attachment of needle cover **127**. The rear housing part **111** comprises most of the device mechanisms. A common drive system includes a spring **141** acting as both as penetration drive and injection drive. The spring acts between housing rear end and an injection head **142** in resilient material giving impact damping and having a generally U-shaped form with legs **143** able to flex laterally in and out and forming a cavity therebetween able to receive, when in an out-flexed position, the plunger **126** rear part during the autoreturn phase. A penetration head aggregate, generally designated **150**, comprises a front generally sleeve-shaped syringe plunger part **151**, having a front surface **152** arranged for contact with barrel rear end or fingergrip **124**, and a rear plunger guide **153**, having a front end **154** extending into the sleeve-like syringe plunger part **151** and a rear end **155** extending well behind the syringe plunger **151**. Between the syringe plunger **151** and the plunger guide **153** a compression damper spring **156** is arranged in slots, biasing the plunger guide **153** towards a rear position relative the syringe plunger **151**. The control system can be said to include an externally accessible releasable lock (not shown) for holding the penetration head in the rear cocked position, and thereby also holding the injection head **142** in its cocked position to be explained, thereby serving both as penetration lock and injection lock. The control system further comprises structures, for sequencing the operation, by flexing the injector head legs **143**. A first such structure comprises tapering surfaces **161** at the syringe plunger **151** rear end, arranged to compress the legs **143** from an intermediate position (shown in FIG. 1A), in which the legs act on the plunger guide **153**, to a narrow position (shown in FIGS. 1B and 1C), in which the legs are freed to land on syringe piston **126** and maintained compressed by channel **162** provided by the plunger guide **153**. The tapering surfaces become active for compression of the legs when the plunger guide moves forward relative the syringe plunger against the force of the damper spring, which is weaker than the drive spring **141**. A second control structure comprises an expansion cavity **163** adapted to allow expansion of the legs **143**, at a position corresponding to plunger **126** final position at empty syringe, to an expanded position (shown in FIG. 1D) allowing the plunger **126** to move into the space between legs **143** under the action of return spring **134** to a needle-hidden syringe position.

In FIG. 1A penetration head **150** is held in a rear cocked position at a short distance from syringe barrel end or fingergrip **124**. The injection head **142** is also held in a rear position since legs **143** rests in a slot on plunger guide **153**. The drive spring **141** is compressed. The container **120** is pressed to a rear needle-hidden position by return spring **134**. In FIG. 1B a trigger (not shown) has been released and drive spring **141** has acted on injection head **142**, which in turn has acted on plunger guide **153** to move syringe plunger **151**, into contact with container barrel or fingergrip **124**,